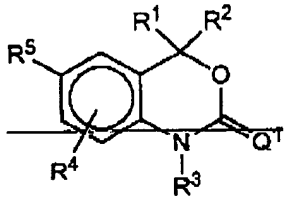
AHPWA25AUSA

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1(Currently Amended). A method of inducing contraception comprising the step of delivering to a female of child-bearing age a composition comprising a compound of ~~formula I or~~ formula II, ~~or a tautomer thereof,~~ in a regimen which involves delivering a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to said female, wherein formula ~~I~~ II is:



~~I~~

~~wherein:~~

~~R^1 and R^2 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, C_2 to C_8 cycloalkyl, phenyl, and thiophene;~~

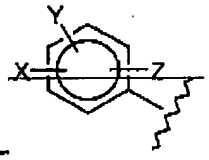
~~or R^1 and R^2 are fused to form a carbon based 3 to 8 membered saturated spirocyclic ring;~~

~~R^3 is H;~~

~~R^4 H;~~

~~R^5 is selected from the group consisting of (i) and (ii):~~

~~(i) a substituted benzene ring having the structure:~~



~~X is selected from the group consisting of halogen, CN, C_1 to C_2 alkyl, substituted C_1 to C_2 alkyl, C_1 to C_2 alkoxy, NO_2, and C_1 to C_2 perfluoroalkyl;~~

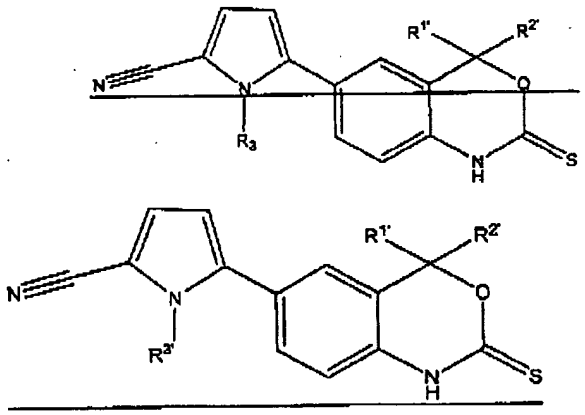
~~Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_3 alkoxy, C_1 to C_4 alkyl, and substituted C_1 to C_4 alkyl; and~~

~~(ii) a five or six membered carbon based heterocyclic ring having in its backbone 1 heteroatom selected from the group consisting of O, S, and NR^6 and having one or two independent substituents selected from the group consisting of H, halogen, CN, C_1 to C_4 alkyl, and substituted C_1 to C_4 alkyl;~~

~~R^6 is selected from the group consisting of H, C_1 to C_3 alkyl, and C_1 to C_4 CO_2alkyl;~~

~~Q^1 is S;~~

~~and formula II is:~~



II

wherein:

$R^{1'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

$R^{2'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

$R^{1'}$ and $R^{2'}$ are joined to form a spirocyclic ring containing 3 to 7 carbon atoms; and

$R^{3'}$ is ~~selected from the group consisting of~~ C_1 to C_4 alkyl;

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of ~~formula I or~~ formula II.

2(Currently Amended). The method according to claim 1, wherein said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator are delivered in a single composition.

3(Currently Amended). The method according to claim 1, wherein said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator are delivered separately.

4(Original). The method according to claim 1, wherein said selective estrogen receptor modulator is selected from the group consisting of EM-800, EM-652, raloxifene hydrochloride, arzoxifene, lasofoxifene, droloxifene, idoxifene, levormeloxifene, centchroman, nafoxidene, tamoxifen citrate, 4-hydroxytamoxifen citrate, clomiphene citrate, toremifene citrate, pipendoxifene, and bazedoxifene.

5(Original). The method according to claim 1, wherein said compound is delivered at a daily dosage of about 0.1 to about 50 mg.

6(Original). The method according to claim 1, wherein said regimen comprises delivering said composition daily for 1 to about 21 days, wherein said regimen is a cycle which is repeated monthly.

7(Currently Amended). ~~Them~~ The method according to claim 1, wherein said selective estrogen receptor modulator is delivered at a daily dosage of about 0.2 to about 100 mg.

8-24(Canceled).

25(Currently Amended). The method according to claim 1 wherein said compound ~~of formula I~~ is selected from the group consisting of ~~6-(3-Chlorophenyl)-4,4-~~

~~dimethyl-1,4-dihydro-benzo[d][1,3]oxazin-2-thione, 4-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-benzo[d][1,3]oxazin-6-yl)-thiophene-2-carbonitrile, 3-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-benzo[d][1,3]oxazin-6-yl)-5-fluorobenzonitrile, 3-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-benzo[d][1,3]oxazin-6-yl)-benzonitrile, 6-(3-fluorophenyl)-4-methyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-4-methylthiophene-2-carbonitrile, tert-Butyl-2-cyano-5-(4,4-dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1H-pyrrole-1-carboxylate, 5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1H-pyrrole-2-carbonitrile, [6-(4,4-dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-pyridin-2-yl]acetonitrile,~~ 5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-methyl-1H-pyrrole-2-carbonitrile, ~~5-(4,4-dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1H-pyrrole-2-carbothiamide, 5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-benzo[d][1,3]oxazin-6-yl)-thiophene-3-carbonitrile,~~ and 5-(4,4-dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-ethyl-1H-pyrrole-2-carbonitrile, ~~4-(1,2-Dihydro-2-thioxospiro[4H-3,1-benzoxazin-4,1-cyclohexan]-6-yl)-2-thiophenecarbonitrile, 5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-2-fluorobenzonitrile, 6-(5-Bromopyridin-3-yl)-4,4-dimethyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 6-(3-Chloro-5-fluorophenyl)-4,4-dimethyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 6-(3-Bromo-5-methylphenyl)-4,4-dimethyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 6-(3-Bromo-5-trifluoromethoxyphenyl)-4,4-dimethyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 3-(1,2-Dihydro-2-thioxospiro[4H-3,1-benzoxazine-4,1-cyclohexan]-6-yl)-5-fluorobenzonitrile, 3-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-5-methylbenzonitrile, 6-(3,5-Dichlorophenyl)-4,4-dimethyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 5-(4,4-Dimethyl-1,2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)isophthalonitrile, 5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-2-furonitrile, 4,4-Diethyl-6-(3-nitrophenyl)-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 6-(3-Chlorophenyl)-4-methyl-4-phenyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 4-Allyl-6-(3-chlorophenyl)-4-methyl-1,4-dihydro-2H-3,1-benzoxazine-2-thione, 3-Chloro-5-(4,4-dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)benzonitrile, 6-(3,5-~~

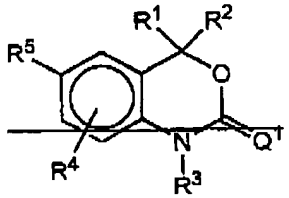
~~Difluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Fluoro 5 methoxyphenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 3 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 5 methoxybenzonitrile, 6 (3 Fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 [3 Fluoro 5 (trifluoromethyl)phenyl] 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (2 Fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3,4 Difluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (4 Fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 3 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 4 fluorobenzonitrile, 6 (2,3 Difluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 3 (8 Bromo 4,4 dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 5 fluorobenzonitrile, 4,4 Dimethyl 6 (3 nitrophenyl) 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Chlorophenyl) 4,4 diethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Methoxyphenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (2 Chlorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 4 Benzyl 6 (3 chlorophenyl) 4 methyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 6 (3 Bromo 5 fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 5 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) thiophene 2 carbonitrile, 3 Fluoro 5 (8 fluoro 4,4 dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl)benzonitrile, 3 (1,2 Dihydro 2 thioxospiro[4H 3,1 benzoxazine 4,1 cyclohexan] 6 yl)benzonitrile, 5 (1,2 Dihydro 2 thioxospiro[4H 3,1 benzoxazine 4,1 cyclohexan] 6 yl) 4 methyl 2 thiophenecarbonitrile, 5 (1,2 Dihydro 2 thioxospiro[4H 3,1 benzoxazine 4,1 cyclohexan] 6 yl) 2 thiophenecarbonitrile, 6 (3 Chloro 4 fluorophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, 5 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 4 propylthiophene 2 carbonitrile, 4 (4,4 Dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl) 2 furonitrile, 4 Butyl 5 (4,4 dimethyl 2 thioxo 1,4 dihydro 2H 3,1 benzoxazin 6 yl)thiophene 2 carbonitrile, 6 (3 Bromophenyl) 4,4 dimethyl 1,4 dihydro 2H 3,1 benzoxazine 2 thione, and 2 (4,4 Dimethyl 2 thioxo 1,4~~

~~dihydro-2H-3,1-benzoxazin-6-yl)thiophene-3-carbonitrile,~~ or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug thereof.

26(Canceled).

27(Currently Amended). The method according to claim 41~~1~~, wherein said compound of formula II is selected from the group consisting of: 5-(4-ethyl-4-methyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-methyl-1H-pyrrole-2-carbonitrile, 5-(4,4-diethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-methyl-1H-pyrrole-2-carbonitrile, 1-methyl-5-(2-thioxo-1,2-dihydrospiro[3,1-benzoxazine-4,1'-cyclobutan]-6-yl)-1H-pyrrole-2-carbonitrile, 1-methyl-5-(2-thioxo-1,2-dihydrospiro[3,1-benzoxazine-4,1'-cyclohexan]-6-yl)-1H-pyrrole-2-carbonitrile, 1-methyl-5-(2-thioxo-1,2-dihydrospiro[3,1-benzoxazine-4,1'-cyclopentan]-6-yl)-1H-pyrrole-2-carbonitrile, 1-methyl-5-[2-thioxo-4,4-bis(trifluoromethyl)-1,4-dihydro-2H- 3,1-benzoxazine-6-yl]-1H-pyrrole-2-carbonitrile, and prodrugs, metabolites, and pharmaceutically acceptable salts thereof.

28(Currently Amended). A pharmaceutical kit useful for inducing contraception, said kit comprising a compound of ~~formula I or~~ formula II and at least one selective estrogen receptor modulator, wherein ~~formula I is:~~



~~I~~

~~wherein:~~

~~R^1 and R^2 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, C_3 to C_8 cycloalkyl, phenyl, and thiophene;~~

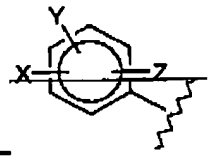
~~or R^1 and R^2 are fused to form a carbon based 3 to 8 membered saturated spirocyclic ring;~~

~~R^3 is H;~~

~~R^4 is H;~~

~~R^5 is selected from the group consisting of (i) and (ii):~~

~~(i) a substituted benzene ring having the structure:~~



~~X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, NO_2, and C_1 to C_3 perfluoroalkyl;~~

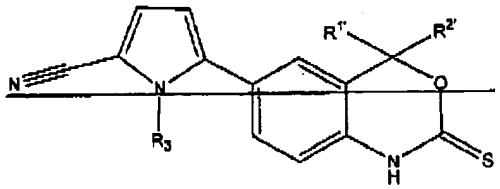
~~Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_3 alkoxy, C_1 to C_4 alkyl, and substituted C_1 to C_4 alkyl; and~~

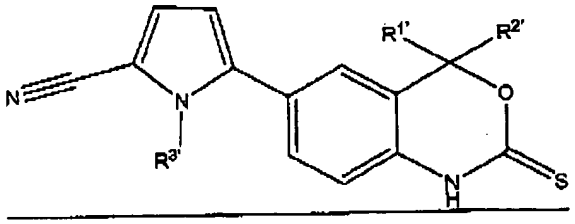
~~(ii) a five or six membered carbon based heterocyclic ring having in its backbone 1 heteroatom selected from the group consisting of O, S, and NR^6 and having one or two independent substituents selected from the group consisting of H, halogen, CN, C_1 to C_4 alkyl, and substituted C_1 to C_4 alkyl;~~

~~R^6 is selected from the group consisting of H, C_1 to C_3 alkyl, and C_1 to C_4 CO_2alkyl;~~

~~Q^1 is S;~~

~~and~~ formula II is:





II

wherein:

$R^{1'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

$R^{2'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

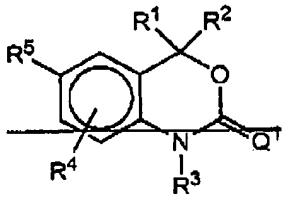
$R^{1'}$ and $R^{2'}$ are joined to form a spirocyclic ring containing 3 to 7 carbon atoms;

and

$R^{3'}$ is C_1 to C_4 alkyl;

~~and~~ or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug thereof.

29(Currently Amended). A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of ~~formula I or~~ formula II~~, or a tautomer thereof,~~ and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein ~~formula I is:~~



~~I~~

~~wherein:~~

~~R^1 and R^2 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_2 to C_6 alkenyl, C_2 to C_6 alkynyl, substituted C_2 to C_6 alkynyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^A, and NR^BCOR^A;~~

~~or R^1 and R^2 are fused to form a ring selected from the group consisting of a), b) and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected from the group consisting of H and C_1 to C_3 alkyl;~~

~~a) a carbon based 3 to 8 membered saturated spirocyclic ring;~~

~~b) a carbon based 3 to 8 membered spirocyclic ring having one or more carbon carbon double bonds; and~~

~~c) a 3 to 8 membered spirocyclic ring having in its backbone one to three heteroatoms selected from the group consisting of O, S and N;~~

~~R^A is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, amino, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;~~

~~R^B is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;~~

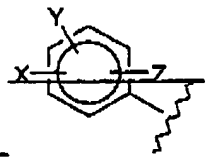
~~R^3 is selected from the group consisting of H, OH, NH_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_2 to C_6 alkenyl, alkynyl, substituted alkynyl, and COR^C;~~

~~R^C is selected from the group consisting of H, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, aryl, substituted aryl, C_1 to C_4 alkoxy, substituted C_1 to C_4 alkoxy, C_1 to C_4 aminoalkyl, and substituted C_1 to C_4 aminoalkyl;~~

~~R^4 is selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_1 to C_6 alkoxy, substituted C_1 to C_6 alkoxy, C_1 to C_6 aminoalkyl, and substituted C_1 to C_6 aminoalkyl;~~

~~R^5 is selected from the group consisting of (i) and (ii):~~

~~(i) a substituted benzene ring having the structure:~~



~~X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3~~

~~thioalkyl, substituted C_1 to C_3 thioalkyl, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, NO_2, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D, $OCOR^D$, and NR^ECOR^D;~~

~~R^D is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;~~

~~R^E is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;~~

~~Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 thioalkyl, and substituted C_1 to C_3 thioalkyl; and~~

~~(ii) a five or six membered carbon based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO_2, and NR^6 and having one or two independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, COR^F, and NR^GCOR^F;~~

~~R^F is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;~~

~~R^G is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;~~

~~R^6 is selected from the group consisting of H, C_1 to C_3 alkyl, and C_1 to C_4 CO_2alkyl;~~

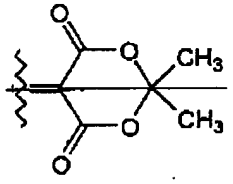
~~Q^1 is selected from the group consisting of S, NR^7, and CR^8R^9;~~

~~R^7 is selected from the group consisting of CN, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO_2CF_3, OR^{11}, and $NR^{11}R^{12}$;~~

~~R^8 and R^9 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO_2, CN, and CO_2R^{10};~~

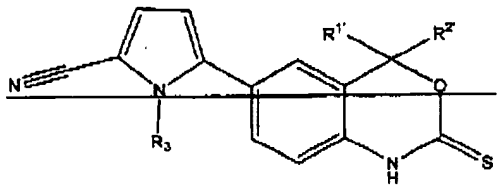
~~R^{10} is selected from the group consisting of C_1 to C_2 alkyl and substituted C_1 to C_3 alkyl;~~

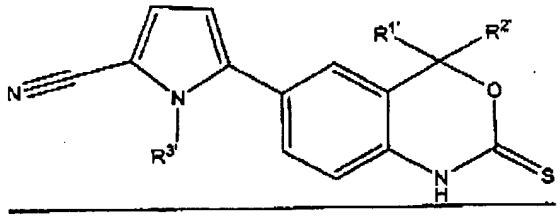
~~or CR^8R^9 comprise a six membered ring having the structure:~~



~~R^{11} and R^{12} are independently selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, aryl, substituted aryl, carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon based heterocyclic ring having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;~~

~~and~~ formula II is:





II

wherein:

$R^{1'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

$R^{2'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

$R^{1'}$ and $R^{2'}$ are joined to form a spirocyclic ring containing 3 to 7 carbon atoms; and

$R^{3'}$ is ~~selected from the group consisting of~~ C_1 to C_4 alkyl;

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of ~~formula I or~~ formula II.

30(Currently Amended). The regimen according to claim 29, comprising delivering said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator separately.

31(Currently Amended). The regimen according to claim 29, comprising delivering said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator in a single composition.

32(Previously Presented). The regimen according to claim 29, further comprising delivering a placebo.

33(Previously Presented). The regimen according to claim 29 which comprises 28 days.

34(Currently Amended). The regimen according to claim 33, wherein said regimen comprises delivering said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator for 14 to 24 days.

35(Currently Amended). The regimen according to claim 33, wherein said regimen comprises:

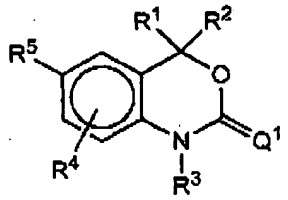
(a) delivering said compound of ~~formula I or~~ formula II and said selective estrogen receptor modulator for the first 14 to 24 days of said 28 day regimen; and

(b) delivering said selective estrogen receptor modulator alone for 1 to 11 days beginning on any day between days 14 and 24.

36(Currently Amended). The regimen according to claim 35, wherein said regimen further comprises:

(c) delivering a placebo for 1 to 10 days during the period of time where said compound of formula II and said selective estrogen receptor modulator are not delivered.

37(Currently Amended). ~~The~~ A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of formula I or II and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein formula I is: ~~according to claim 33~~



I

wherein:

R^1 and R^2 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_2 to C_6 alkenyl, C_2 to C_6 alkynyl, substituted C_2 to C_6 alkynyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8

cycloalkyl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^A, and NR^BCOR^A;

or R^1 and R^2 are fused to form a ring selected from the group consisting of a), b) and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected from the group consisting of H and C_1 to C_3 alkyl;

a) a carbon-based 3 to 8 membered saturated spirocyclic ring;

b) a carbon-based 3 to 8 membered spirocyclic ring having one or more carbon-carbon double bonds; and

c) a 3 to 8 membered spirocyclic ring having in its backbone one to three heteroatoms selected from the group consisting of O, S and N;

R^A is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, amino, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^B is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

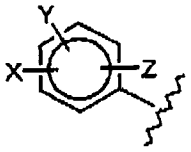
R^3 is selected from the group consisting of H, OH, NH_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_6 alkenyl, substituted C_3 to C_6 alkenyl, alkynyl, substituted alkynyl, and COR^C;

R^C is selected from the group consisting of H, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, aryl, substituted aryl, C_1 to C_4 alkoxy, substituted C_1 to C_4 alkoxy, C_1 to C_4 aminoalkyl, and substituted C_1 to C_4 aminoalkyl;

R^4 is selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_1 to C_6 alkoxy, substituted C_1 to C_6 alkoxy, C_1 to C_6 aminoalkyl, and substituted C_1 to C_6 aminoalkyl;

R^5 is selected from the group consisting of (i) and (ii):

(i) a substituted benzene ring having the structure:



X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, NO_2, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D, $OCOR^D$, and NR^ECOR^D;

R^D is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^E is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 thioalkyl, and substituted C_1 to C_3 thioalkyl; and

(ii) a five or six membered carbon-based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO_2, and NR^6 and having one or two independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, COR^F, and NR^GCOR^F;

R^F is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^G is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

R^6 is selected from the group consisting of H, C_1 to C_3 alkyl, and C_1 to C_4 CO_2alkyl;

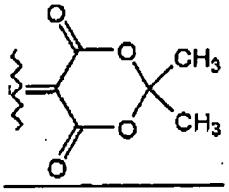
Q^1 is selected from the group consisting of S, NR^7, and CR^8R^9;

R^7 is selected from the group consisting of CN, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO_2CF_3, OR^{11}, and $NR^{11}R^{12}$;

R^8 and R^9 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO_2, CN, and CO_2R^{10};

R^{10} is selected from the group consisting of C_1 to C_3 alkyl and substituted C_1 to C_3 alkyl;

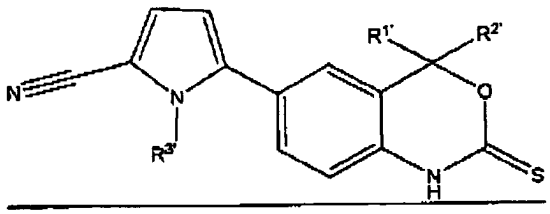
or CR^8R^9 comprise a six membered ring having the structure:



R^{11} and R^{12} are independently selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring

having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;

and formula II is:



II

wherein:

$R^{1'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

$R^{2'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

$R^{1'}$ and $R^{2'}$ are joined to form a spirocyclic ring containing 3 to 7 carbon atoms; and

$R^{3'}$ is C_1 to C_4 alkyl;

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of formula I or formula II, wherein said regimen comprises:

(a) delivering said compound of formula I or formula II for the first 18 to 21 days of a 28 day regimen; and

(b) delivering said selective estrogen receptor modulator alone for 1 to 7 days following delivery of (a).

38(Currently Amended). ~~The~~ A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of formula I or II and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein formula I is: ~~according to claim 33~~

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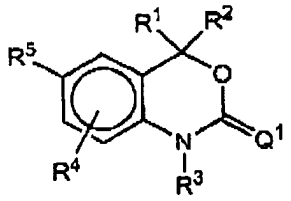


I

wherein:

R^1 and R^2 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_2 to C_6 alkenyl; C_2 to C_6 alkynyl, substituted C_2 to C_6 alkynyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^A, and NR^BCOR^A;

or R^1 and R^2 are fused to form a ring selected from the group consisting of a), b) and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected from the group consisting of H and C_1 to C_3 alkyl;

a) a carbon-based 3 to 8 membered saturated spirocyclic ring;

b) a carbon-based 3 to 8 membered spirocyclic ring having one or more carbon-carbon double bonds; and

c) a 3 to 8 membered spirocyclic ring having in its backbone one to three heteroatoms selected from the group consisting of O, S and N;

R^A is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, amino, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^B is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

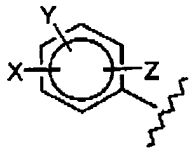
R^3 is selected from the group consisting of H, OH, NH_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_6 alkenyl, substituted C_3 to C_6 alkenyl, alkynyl, substituted alkynyl, and COR^C;

R^C is selected from the group consisting of H, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, aryl, substituted aryl, C_1 to C_4 alkoxy, substituted C_1 to C_4 alkoxy, C_1 to C_4 aminoalkyl, and substituted C_1 to C_4 aminoalkyl;

R^4 is selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_1 to C_6 alkoxy, substituted C_1 to C_6 alkoxy, C_1 to C_6 aminoalkyl, and substituted C_1 to C_6 aminoalkyl;

R^5 is selected from the group consisting of (i) and (ii):

(i) a substituted benzene ring having the structure:



X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, NO_2, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D, $OCOR^D$, and NR^ECOR^D;

R^D is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^E is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 thioalkyl, and substituted C_1 to C_3 thioalkyl; and

(ii) a five or six membered carbon-based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO_2, and NR^6 and having one or two independent substituents selected from the group consisting

of H, halogen, CN, NO_2, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, COR^F, and NR^GCOR^F;

R^F is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^G is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

R^6 is selected from the group consisting of H, C_1 to C_3 alkyl, and C_1 to C_4 CO_2alkyl;

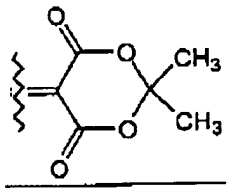
Q^1 is selected from the group consisting of S, NR^7, and CR^8R^9;

R^7 is selected from the group consisting of CN, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO_2CF_3, OR^{11}, and $NR^{11}R^{12}$;

R^8 and R^9 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO_2, CN, and CO_2R^{10};

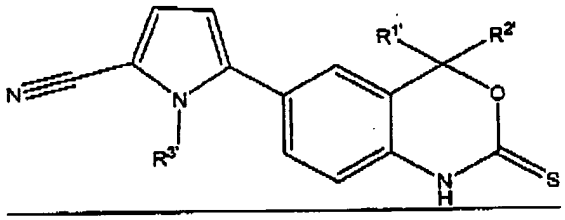
R^{10} is selected from the group consisting of C_1 to C_3 alkyl and substituted C_1 to C_3 alkyl;

or CR^8R^9 comprise a six membered ring having the structure:



R^{11} and R^{12} are independently selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;

and formula II is:



II

wherein:

$R^{1'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

$R^{2'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

$R^{1'}$ and $R^{2'}$ are joined to form a spirocyclic ring containing 3 to 7 carbon atoms; and

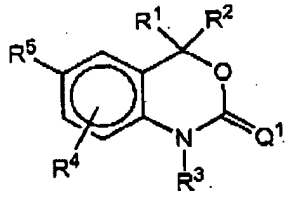
$R^{3'}$ is C_1 to C_4 alkyl;

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of formula I or formula II, wherein said regimen comprises:

(a) delivering said compound of formula I or formula II and an estrogen for the first 21 days of a 28 day regimen; and

(b) delivering said selective estrogen receptor modulator alone from days 22 to 24 of said 28 day regimen ~~for 1 to 4 days~~.

39(Currently Amended). ~~The method~~ A contraceptive regimen comprising the periodic and discontinuous delivery of a compound of formula I or II and a pharmaceutically effective amount of one or more of a selective estrogen receptor modulator to a female of child-bearing age, wherein formula I is: ~~according to claim 29~~



I

wherein:

R^1 and R^2 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_2 to C_6 alkenyl, C_2 to C_6 alkynyl, substituted C_2 to C_6 alkynyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^A, and NR^BCOR^A;

or R^1 and R^2 are fused to form a ring selected from the group consisting of a), b) and c), wherein said ring is optionally substituted by from 1 to 3 substituents selected from the group consisting of H and C_1 to C_3 alkyl;

a) a carbon-based 3 to 8 membered saturated spirocyclic ring;

b) a carbon-based 3 to 8 membered spirocyclic ring having one or more carbon-carbon double bonds; and

c) a 3 to 8 membered spirocyclic ring having in its backbone one to three heteroatoms selected from the group consisting of O, S and N;

R^A is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, amino, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^B is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

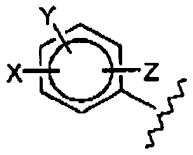
R^3 is selected from the group consisting of H, OH, NH_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, substituted C_3 to C_6 alkenyl, alkynyl, substituted alkynyl, and COR^C;

R^C is selected from the group consisting of H, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, aryl, substituted aryl, C_1 to C_4 alkoxy, substituted C_1 to C_4 alkoxy, C_1 to C_4 aminoalkyl, and substituted C_1 to C_4 aminoalkyl;

R^4 is selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_1 to C_6 alkoxy, substituted C_1 to C_6 alkoxy, C_1 to C_6 aminoalkyl, and substituted C_1 to C_6 aminoalkyl;

R^5 is selected from the group consisting of (i) and (ii):

(i) a substituted benzene ring having the structure:



X is selected from the group consisting of halogen, CN, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, NO_2, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, COR^D, $OCOR^D$, and NR^ECOR^D;

R^D is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^E is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

Y and Z are independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 thioalkyl, and substituted C_1 to C_3 thioalkyl; and

(ii) a five or six membered carbon-based heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO_2, and NR^6 and having one or two independent substituents selected from the group consisting of H, halogen, CN, NO_2, C_1 to C_4 alkyl, substituted C_1 to C_4 alkyl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, substituted C_1 to C_3 aminoalkyl, C_1 to C_3 perfluoroalkyl, substituted C_1 to C_3 perfluoroalkyl, 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted 5 or 6 membered carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, C_1 to C_3 thioalkyl, substituted C_1 to C_3 thioalkyl, COR^F, and NR^GCOR^F;

R^F is selected from the group consisting of H, C_1 to C_3 alkyl, substituted C_1 to C_3 alkyl, aryl, substituted aryl, C_1 to C_3 alkoxy, substituted C_1 to C_3 alkoxy, C_1 to C_3 aminoalkyl, and substituted C_1 to C_3 aminoalkyl;

R^G is selected from the group consisting of H, C_1 to C_3 alkyl, and substituted C_1 to C_3 alkyl;

R^6 is selected from the group consisting of H, C_1 to C_3 alkyl, and C_1 to C_4 CO_2alkyl;

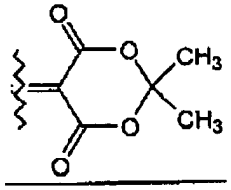
Q^1 is selected from the group consisting of S, NR^7, and CR^8R^9;

R^7 is selected from the group consisting of CN, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, SO_2CF_3, OR^{11}, and $NR^{11}R^{12}$;

R^8 and R^9 are independent substituents selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_3 to C_8 cycloalkyl, substituted C_3 to C_8 cycloalkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, NO_2, CN, and CO_2R^{10};

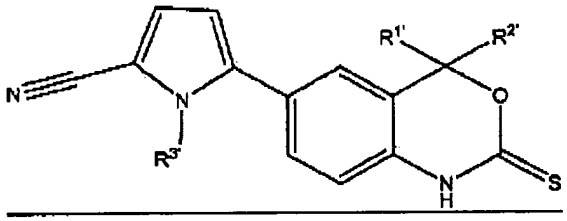
R^{10} is selected from the group consisting of C_1 to C_3 alkyl and substituted C_1 to C_3 alkyl;

or CR^8R^9 comprise a six membered ring having the structure:



R^{11} and R^{12} are independently selected from the group consisting of H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, aryl, substituted aryl, carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, substituted carbon-based heterocyclic ring having in its backbone 1 to 3 heteroatoms, acyl, substituted acyl, sulfonyl, and substituted sulfonyl;

and formula II is:



II

wherein:

$R^{1'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl;

$R^{2'}$ is selected from the group consisting of methyl, ethyl, and trifluoromethyl; or

$R^{1'}$ and $R^{2'}$ are joined to form a spirocyclic ring containing 3 to 7 carbon atoms; and

$R^{3'}$ is C_1 to C_4 alkyl;

or a pharmaceutically acceptable salt, tautomer, metabolite, or prodrug of formula I or formula II, wherein said regimen comprises 28 days and the steps of:

(a) a first phase of the compound of formula I or formula II and said selective estrogen receptor modulator to be administered ~~on~~ for the first ~~days~~ 14 to 24 days of said regimen;

(b) a second phase of said selective estrogen receptor modulator to be administered ~~on days~~ for 1 to 11 days of said regimen beginning on any day between days 14 and 24; and

(c) a third phase of an orally and pharmaceutically acceptable placebo for ~~days~~ 1 to 10 days ~~of said regimen or a third phase~~ in which ~~component~~ phase (a) or (b) is not administered ~~for days~~ 1 to 10 days ~~of said regimen~~.

40(Currently Amended). The ~~method~~ regimen according to claim 39, wherein:

(a) said first phase comprises 14 days;

(b) said second phase comprises 7 days; and

(c) said third phase comprises 7 days.